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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,292	04/02/1999	DONNA G. ALBERTSON	023070-09140	3543

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/285,292

Applicant(s)

ALBERTSON ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 03/07/05.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Request for Continued Examination

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 24, 2006 has been entered.

2. Claims 1-12 and 14-17 are pending.

Claim 1 has been amended.

Claims 1-12 and 14-17 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objection

Specification

4. The specification is no longer objected to because Applicants have removed the reference to GenBank accession numbers U60669 and S78775 in claim 1.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

5. The new matter rejection of claim 15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants pointing out support for the recitation "...at the 95 percent or greater confidence level." on page 42, lines 7-11, see Remarks submitted March 24, 2006, page 6.

6. The rejection of claims 1-12 and 14-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in light of amendments to the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-12 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In light of Applicants' current claims this rejection initially set forth in the Action mailed May 04, 2004 is once again applied to the examined claims. Applicants' claims are directed to a method of prognosticating cancer by detecting the level of CYP24 by several means, such as comparative genomic hybridization (CGH) and detection of CYP24 mRNA. The written description is not commensurate in scope with these method claims drawn to CYP24, which have not been adequately described nor evidenced to be in the possession of Applicants. There is no corresponding sequence identifier, nor is it clear from the claims that there is only one sequence of the candidate cancer marker. Information provided in the specification sets forth "'CYP24 gene' is a DNA sequence that encodes a 24-hydroxylase enzyme...The term gene can refer to a mutated copy of the gene, or a fragment of the gene", see page 7, lines 10-12. It follows that the acronym *CYP24* encompasses a genus of molecules, such as nucleic acids, proteins and mRNA that are not necessarily wild type forms of the *CYP24*. The term reads on a plethora of variant, mutated and alternate forms of *CYP24*. Applicants are not in possession of the entire genus of *CYP24* molecules embraced by the claim language. "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identify characteristics sufficient to show that the applicant was in possession of the claimed invention", see Official Gazette, 1242 OG 172, January 30, 2001.

Art Unit: 1643

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

The skilled artisan cannot envision the detailed structure of either BF-14 or BPI-14 and conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The product itself is required. Applicants have not described CYP24 with sufficient particularity such that one skilled in the art would recognize that the Applicants had possession of the claimed invention. It is not clear from the instant application was filed that there was only one human sequence of CYP24. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved

Art Unit: 1643

by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

9. Claims 1-12 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting CYP24 mRNA in human breast tumor *in vitro* specimens treated with 1,25-dihydroxyvitamin D-3 comprising RT-PCR, does not reasonably provide enablement for a method of detecting a predisposition to any cancer comprising detecting the level of CYP24 nucleic acid or CYP24 protein in a biological sample and comparing said level with the level from a control sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The broad term "cancer" encompasses several organ systems with different and distinct histopathologies and various etiologic causative agents. The claims read on embodiments that are not enabled, i.e. any cancer type and forecasting whether or not a person will develop cancer. In essence, the breadth of the methodology claimed is

Art Unit: 1643

not commensurate with the scope of the claims. There is insufficient guidance in the specification providing methodology consistent with the claims. Applicants' specification outlines detection of the level of CYP24 by measuring the level of CYP24 mRNA in human breast cancer cell lines and tumors with and without induction by 1,25 - dihydroxyvitamin D₃ evaluated by RT-PCR. Applicants' Figure 3 provides evidence that mRNA corresponding to CYP24 and vitamin D receptor (VDR) from human breast tumor cell lines can be detected, see page 18, lines 3-9; page 53, lines 15-27; and page 58, lines 5-7. In essence there is PCR amplification of specific CYP24 target RNA from either total RNA or mRNA. However, normal control data is not of record, hence one of ordinary skill in the art could not definitely assess whether or not the said method could lead one to detect the predisposition to any cancer including breast cancer in light of the data provided and the prior art of record that seems contrary to what Applicants assert.

There would need to be some valid amount of direction or guidance, as well as presence or absence of working examples presented in the specification that would enable one skilled in the art to perform the method as presented in the recited claims. It appears that undue experimentation would be required of one skilled in the art to practice the instant claimed invention using the teachings of the specification. See Ex parte Forman, 230 USPQ 546 BPAI, 1986.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

Art Unit: 1643

(571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

01 June 2006